

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB
Display Date 5-28-03
Publication Date 5-29-03
Certifier M. Hawkins

Gastrointestinal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastrointestinal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 25 and 26, 2003, from 8:30 a.m. to 5 p.m.

Location: Marriott Washingtonian Center, The Ballrooms, 9751 Washingtonian Blvd., Gaithersburg, MD, 301-590-0044.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-6758, or e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12538. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 25, 2003, the committee will discuss new drug application (NDA) 21-597, SEROSTIM (somatropin), Serono, Inc., for the treatment of short bowel syndrome in patients receiving specialized nutritional

oc03151

3966

NM

support. SEROSTIM therapy should be used in conjunction with optimal management of short bowel syndrome. On June 26, 2003, the committee will discuss NDA 21-525, PHOTOFRIN (porfirmer sodium), Axcan Scandipharm, Inc. Photodynamic therapy with PHOTOFRIN is indicated for the ablation of high-grade dysplasia in Barrett's esophagus among patients who refuse esophagectomy and who are in overall good health.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 16, 2003. Oral presentations from the public will be scheduled between 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 16, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

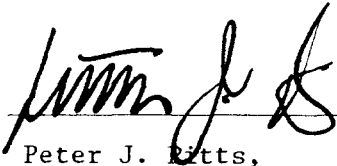
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Thomas H. Perez at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 5/22/03
May 22, 2003.

oc03151



Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

